

Vaccine procurement and self-sufficiency in developing countries

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This paper discusses the movement toward self-sufficiency in vaccine supply in developing countries (and countries in transition to new economic and political systems) and explains special supply concerns about vaccine as a product class. It traces some history of donor support and programmes aimed at self-financing, then continues with a discussion about self-sufficiency in terms of institutional capacity building. A number of deficiencies commonly found in vaccine procurement and supply in low- and middle-income countries are characterized, and institutional strengthening with procurement technical assistance is described. The paper also provides information about a vaccine procurement manual being developed by the United States Agency for International Development (USAID) and the World Health Organization (WHO) for use in this environment. Two brief case studies are included to illustrate the spectrum of existing capabilities and different approaches to technical assistance aimed at developing or improving vaccine procurement capability. In conclusion, the paper discusses the special nature of vaccine and issues surrounding potential integration and decentralization of vaccine supply systems as part of health sector reform.

Introduction and background

Until quite recently, many developing-country governments and other stakeholders thought of vaccines as donor-supplied commodities. For the most part, low-income and some middle-income countries did not include them in annual health budgets. Donor organizations provided Expanded Programme on Immunization (EPI) vaccines¹ and related commodities from their own domestic sources or arranged with the United Nations Children's Fund (UNICEF) or the Pan American Health Organization (PAHO) to purchase and deliver vaccines on their behalf from a pool of prequalified manufacturers assessed by the World Health Organization (WHO). At the same time, UNICEF and PAHO offered – and continue to offer – procurement services to many low- and middle-income countries that have the means to pay for their own requirements but lack the skills and/or infrastructure required for obtaining safe and effective, reasonably priced vaccine from the international market-place. In certain cases, WHO has also acted as a procurement agent and remains willing to do so.

Before 1991, republics of the former Soviet Union received EPI vaccines and other vaccines through a centrally planned system in Moscow, mainly from production facilities located within the borders of the Russian republic. When the Soviet Union collapsed at the end of 1991, the Newly Independent States (NIS) outside of the Russian Federation² found themselves with very little vaccine manufacturing capacity. Financial support from Moscow, in the form of transfer payments, ceased, and government health programmes went into a tailspin. With a virtual collapse of banking systems in the region, cross-border trading became almost impossible, even for the

few republics with rubles available to purchase vaccine from Moscow. Thus, immunization programmes were suddenly cut off from their traditional Soviet suppliers, and from one another, by economic and political barriers. A shortage of vaccine developed rather quickly, and on its heels there was a significant upswing in vaccine-preventable disease, notably diphtheria.

The NIS faced three closely related problems with respect to immunization and vaccine-preventable diseases: maintenance of basic immunization services, eradication of poliomyelitis, and control of the NIS-wide epidemic of diphtheria (WHO 1996). All of the NIS (except the Russian Federation) required external support in acquiring the commodities necessary to confront these problems, and all were in need of technical assistance. From 1992 to 1994, USAID provided emergency shipments of vaccine and related commodities to Georgia, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan and Uzbekistan.

The NIS was not an isolated trouble spot with regard to vaccine supply. By the early 1990s, many international donor organizations had begun to realize they could not continue to meet the ever-growing demand for health commodities in the developing world. In 1993, the World Bank suggested broad changes in health funding and allocation of resources (World Bank 1993). With the advent of deep budget cuts in US foreign aid, financial downturns in other countries, and serious new health challenges across the globe, as well as the deepening crisis in the NIS, donors began to reserve commodity assistance for the most needy countries. The terms 'independence' and 'self-sufficiency' started to appear in the context of vaccine supply.

Vaccine Independence Initiative

In 1992, a Vaccine Independence Initiative (VII) aimed at supporting 'self-sufficiency' in vaccine supply was undertaken by UNICEF in collaboration with USAID. Modelled on a programme established by PAHO for Latin America in 1979, the VII encourages donors to 'capitalize' revolving funds for candidate middle-income countries as one-time assistance. These funds provide 'start-up' cash in convertible currency so that participating governments can move away from commodity donations and begin purchasing vaccine through UNICEF's procurement services.³ Under this programme, countries use capitalized revolving funds to initiate orders with UNICEF and repay the revolving funds upon receipt of each vaccine shipment; cash on deposit with UNICEF supports subsequent vaccine orders. In cases where UNICEF has sufficient requirements for local currency to cover its in-country programme and operating costs, it is sometimes able to accept repayment to the revolving funds in local currency (calculated at the current United Nations rate of exchange). Unfortunately, this has not applied to rubles and other national currencies of the NIS.

Targeted assistance

In 1994, WHO and UNICEF issued a vaccine-supply strategy calling for all countries, including the poorest, to start paying for at least some fraction of their vaccine needs immediately, leading eventually toward governments covering all the costs of their routine vaccine needs. The strategy also suggested that UNICEF's vaccine-supply assistance should be preferentially targeted toward the poorer and smaller countries; the larger and better-off developing countries were strongly encouraged to immediately become self-financing (UNICEF 1994). Countries were plotted on a grid according to economic and population factors, roughly dividing them into three categories: those eligible for donated vaccine (i.e. the smallest, most indigent countries); those encouraged to use VII, UNICEF procurement services, and other types of assistance (i.e. the more potentially self-reliant of the poor countries); and countries that were 'on their own' either immediately or in the near future (Davey 1996). Meanwhile, the international community was pouring emergency assistance into the NIS and the Baltic States in the form of vaccine to combat the growing diphtheria problem and to maintain primary immunization.

International Immunization Coordinating Committee

In July 1994, in Kyoto, Japan, a group of international development agencies and government representatives formed an Interagency Immunization Coordinating Committee (IICC) in order to assist the NIS in controlling diseases preventable by immunization, ensuring primary vaccination of children, and attaining vaccine independence. Despite substantial donations, the diphtheria epidemic remained a major problem, so the Committee launched an emergency appeal for support in June 1995. At its third meeting in Istanbul, Turkey, in November 1995, the Committee also reiterated its position that the ultimate goal was for all of the NIS to become self-sufficient in vaccine supply, primarily through purchase of high-quality vaccines (WHO 1996).

VII in the Former Soviet Union

Concurrent with the formation of the IICC, the Japanese government and UNICEF established a VII-like mechanism for the NIS. No revolving funds were involved, nor was repayment required. Instead, vaccine for primary series immunization would be provided to participating countries in declining amounts over a 5-year period. Typically, the entire annual requirement was covered by the donor in the first year. In the second year, 80% was provided by the donor, and the country was committed to purchase the other 20% from UNICEF with its own hard currency. In the third year, the ratio changed again until, by the year 2000, all vaccine for infant immunization would be covered by the participating country through hard currency purchases from UNICEF. The same scheme of reducing funding (20% per year, down to zero after 5 years) was announced by the Japanese government (through the Japan International Cooperation Agency) in Zambia in late 1997, in a letter delivered to the Ministry of Health (Feilden and Nielsen 1998). While these quasi-VIIs were being set up, donor organizations filled the primary series vaccine gap.

Self-sufficiency in the context of health sector reform

Much of the discussion above suggests that 'self-sufficiency' in vaccine supply is defined by the availability of funds to pay for the vaccine. However, large donor and development organizations such as USAID, the World Bank (World Bank 1993) and WHO (WHO 1995) have actually embraced a much broader vision of self-sufficiency in the context of health sector reform: development of institutional capacity and adoption of modern management principles from the private sector. This perspective strongly implies that countries should begin to acquire the skills and infrastructure needed to independently and effectively manage procurement processes that will deliver the best value for the price paid and ensure a continuous supply of vaccine of known good quality and related health care commodities, both now and in the future.

In theory, countries wishing to procure vaccines have two choices: they can either purchase directly from vaccine manufacturers (or their local agents) or indirectly through UNICEF or PAHO, assuming those agencies are willing to provide vaccine to the purchasing country (Hausdorff 1996). In terms of price, UNICEF and PAHO receive substantial discounts from manufacturers since they are high-volume purchasers, but the addition of an administrative fee, e.g. 6–8% for UNICEF (Feilden and Battersby 1997), has frequently brought the total cost up to, or beyond, the lowest vaccine prices offered directly to public-sector markets (USAID/BASICS/PATH 1996). Very small annual requirements may change this picture somewhat, depending upon supplier pricing policies. Assuming nearly equal costs, the advantages and disadvantages of purchasing through UNICEF or PAHO are virtually the same: the process does not require countries to develop an institutional capability for vaccine procurement in the international market-place nor to put in place a regulatory structure to ensure the quality of the

vaccine it uses. It reduces procurement to estimates of annual need plus periodic requests for shipment, and it provides an implied assurance of quality, since all manufacturers who sell vaccine into the United Nations system must be assessed and approved for that purpose by WHO. Countries are not encouraged to move toward a broader meaning of self-sufficiency by developing skills and infrastructure for vaccine procurement.

It is safe to say that all countries, including those in the NIS, currently have some degree of international procurement capability. However, purchasing safe, effective vaccines is not a simple, straightforward task. It requires specialized knowledge, special handling procedures, a competent regulatory environment, and the political will to develop these prerequisites. It also requires a vaccine management entity with the authority, as well as an ability, to accurately monitor geographic distribution of stores and consumption rates, forecast national requirements, and ensure that funds for vaccine procurement are a regular and recurring part of national or sub-national planning and budgeting cycles.

Because vaccines are biological products, the characteristics and quality of each batch can vary. Although vaccines produced in industrialized countries are subject to adequate systems of quality assurance and meet agreed-upon international standards, nearly half of the world's vaccine supply is produced in non-industrialized countries. Manufacturers in these countries do not always produce vaccines under conditions that ensure the safety, potency, and efficacy of their products (WHO 1995). Thus, questionable vaccine sources must be systematically eliminated by the procurement process.

The inherent quality (or lack of quality) of vaccine leaving a manufacturer's facility is not the only concern. Temperature and storage time must be controlled from the point of manufacture to the point of use in order to retain potency. This requires special arrangements for cold chain packing, air shipment, expedited customs clearance, and delivery to cold storage. Refrigerated storage capacity at the central level and at the periphery, as well as temperature-controlled transport between levels, must be coordinated.

More than a few developing and transitional countries with cash to spend on vaccine are choosing to go directly into the international market-place, even though a number of them may be, as yet, ill equipped for purchasing safe, effective vaccines on their own. Some are motivated by sovereignty, security, or national pride issues. Others simply want to exercise closer control over the type and quantity of their vaccine supplies, and the terms and conditions of their contracts, than purchasing through UNICEF will normally allow. Source, price, vial size, labelling, and payment terms are of concern, as are contract execution issues, particularly on-time deliveries. UNICEF's payment-in-advance requirement is problematic in many cases, particularly in countries where government procurement rules forbid it. Although using a commercial letter of credit could guarantee payment to UNICEF and circumvent these difficulties for both parties, UNICEF is not yet able to offer this option. In addition,

UNICEF has been limited in its ability to provide new and non-EPI vaccines. In the case of newer vaccines such as hepatitis B, manufacturers' representatives have actively solicited business from Ministries of Health (MOH) and have sometimes convinced them to pay inordinately high prices or commit to marketing plans of dubious public health value.

Field observations

Recent fieldwork by USAID and WHO consultants has identified some common deficiencies in the direct vaccine procurement undertaken by developing and transitional countries.

In 'new' systems (such as those found in former Socialist countries):

- Personnel charged with obtaining vaccines and related supplies often have very little knowledge about standard international contracting procedures or international trade conventions, let alone experience specific to vaccine procurement. They need practical advice, information, and answers to questions such as: 'Where can we get it?', 'How much does it cost?', 'How do we interact with suppliers?', 'How do we know it's safe?' and 'How can we avoid being cheated?'
- The procurement infrastructure is inadequate, often without formal organization and clear assignment of responsibility; systems, policies, and procedures are lacking or inconsistent; documentation and reference materials are rare.
- Personnel responsible for vaccines must discover and deal with newly instituted laws and regulations and stay abreast of revisions in the country's national plans and budgets.
- Accurate information regarding *regional* procurement, distribution, and consumption of vaccine supplies is unavailable at the central level for estimating overall national requirements.
- National budgets for immunization programmes are inadequate for providing all EPI antigens and sometimes leave regional subdivisions 'on their own' with regard to making up the shortfall. As a result, procuring and monitoring of supplies become decentralized and largely unregulated as regions purchase their own vaccines from independent suppliers. Because of greatly reduced procurement sizes, difficulty in accessing resources such as UNICEF, and poor procurement practices, this decentralization almost always results in inefficient expenditure of scarce resources and can pose threats to vaccine quality.
- There is no method of ensuring quality.

In established systems (such as those found in African countries):

- Systems are sometimes fragmented to the degree that no single person can comprehend the whole, key players have little opportunity to interact, and general procurement offices and tender boards have little knowledge of the special nature of vaccines.
- Personnel lack training and information specific to vaccines, and often have little experience with international trade procedures.

- Systems are undergoing fundamental organizational changes in connection with health sector reform.
- Annual budgets for immunization programmes are rendered inadequate by currency devaluations.

In new and established systems:

- Regulatory infrastructure specific to biologicals is often insufficient for ensuring delivery of safe, effective vaccine. (WHO recommends that non-vaccine-producing countries have a national regulatory authority established through appropriate legislation that is independent, competent, and at a minimum, carries out licensing, surveillance, lot-release activities, and has access to appropriate laboratory services.)
- Funds for vaccine procurement are limited and often inadequate.
- Managers and other decision-makers often lack the skills and tools to make systematic value-for-price assessments.
- Hard currency may be difficult to obtain.
- Procurement practices do not provide an appropriate level of competition, resulting in prices that are higher than necessary and contracts that do not protect the purchaser from injurious demands or failures of the supplier.

Establishing and strengthening procurement capabilities

Developing and transitional countries are beginning to seek help with establishing or improving their national capacities for vaccine procurement. Some have experienced problems with high prices or the receipt of unacceptable products. Others, faced with a government mandate to begin purchasing vaccines in the international market-place, have no idea how to proceed. In addition, decision-makers are beginning to take self-sufficiency seriously and are searching for options and information that will help them maximize the scarce funds they have available for vaccine and related items.

For a number of years, a specialized niche of technical assistance has been developing around vaccine supply systems in low- and middle-income countries. In 1992, USAID (through its REACH and BASICS projects and subcontracts with PATH) began working to strengthen vaccine procurement capability in several NIS countries and later extended its efforts into Africa, working alongside WHO and UNICEF programmes in Zimbabwe. The USAID approach to helping countries improve their vaccine procurement has been geared to identifying and training motivated, task-level personnel in country as well as advising decision-makers and managers about procurement matters.

While this effort has been ongoing, the WHO/Global Programme for Vaccines and Immunization/Vaccine Supply and Quality Unit has focused on policy development and legislation for regulatory control of vaccines in developing countries, i.e. a 'top-down' approach to helping countries improve vaccine procurement and quality control. Based on field observations and requests for assistance, the need for concurrent 'bottom-up' skills development at the task level, and 'top-down' infrastructure development at the policy/regulatory level, is clear.

Harmonization of policies

In late 1996, USAID and WHO began a combined effort to harmonize policies surrounding vaccine quality issues with a process for vaccine procurement that could be used both jointly and by others to strengthen systems in developing and transitional countries. Based on earlier procurement reference documents developed by PATH and USAID/BASICS during 1993–96, a new manual was drafted that incorporates WHO policy statements and introduces techniques and infrastructure for assuring vaccine quality. Reviewers and contributors have included UNICEF, United States and European vaccine manufacturers, pharmaceutical manufacturers' associations, and regulatory agencies, including the United States Food and Drug Administration and the Department of Commerce.

The policies and procedures reflected in the new USAID/WHO manual were also coordinated with a set of training modules developed by the International Center for Childhood and the Family, Paris, entitled *Vaccines: Financing and Management*. In addition, the World Bank has considered including special clauses for vaccine procurement in its next revision of *Standard Bidding Documents: Procurement of Pharmaceuticals and Vaccines*.

The new, joint manual *Procurement of Vaccines for Public-Sector Programmes* (to be published by WHO), provides options, procedures, and step-by-step instructions for vaccine procurement, examples of vaccine specifications, and quality assurance information geared to hands-on procurement personnel. It also provides extensive reference material, including information on shipping and international trade. While many parts of it contain useful, stand-alone material, this document is most effective when used in conjunction with on-site procurement technical assistance. A flow chart of the procurement process (based on modified World Bank requirements) will also be available as a training tool and model.

Procurement technical assistance

The specialized procurement technical assistance undertaken by USAID through BASICS and PATH is keyed to specific needs of the participating country. Economic and political factors, the immunization system in general, and specific vaccine supply practices are examined during an initial assessment visit. Concurrent with a WHO-sponsored assessment of vaccine quality control capabilities, the national regulatory environment for biologicals and the infrastructure around international commerce, such as international banking capabilities, access to hard currency, customs practices, and taxation on imports, as well as the warehousing and distribution infrastructure, are all considered. Finally, forecasting methods, budgeting and financing, specifications, and current procurement practices (especially competitive procedures, methods for selection, award of orders, and standard contract wording) are examined. Probably the most important aspect of the assessment process is identifying personnel who are, or will be, responsible for hands-on vaccine procurement activities. Together

with assessing acute needs and long-term plans, these elements establish a basis for individualized programmes of technical assistance.

Depending upon findings and circumstances, the assessment phase may be followed by a participatory procurement exercise in which vaccine is purchased on a competitive basis from the international market under the supervision of a specialist in the field. In some cases, more elaborate infrastructure will be developed; for example, a procurement office or a dedicated procurement unit with written policies and procedures, job descriptions, and an organizational chart could be established. Sometimes the most appropriate assistance – recognizing an intended or *de facto* decentralization of the procurement system – is provided through countrywide seminars, workshops, or presentations aimed at educating decision-makers and other stakeholders. Occasionally, assistance will be limited to addressing a current supply-related emergency or helping a decision-maker assess options based on value-for-price considerations.

Two case studies

The following country situations represent two extremes of existing capability and infrastructure found in low- and middle-income countries. They illustrate two different approaches to technical assistance aimed at developing or strengthening vaccine procurement.

Moldova

The difficult economic and political circumstances encountered in Moldova in 1996 were typical of the NIS in the years immediately following the collapse of the Soviet Union. USAID's Office of Health and Nutrition had been involved in providing humanitarian and development aid for child immunization services since 1992, using the BASICS project and its predecessor, the REACH project, as the implementing entities. Through technical assistance provided by REACH and then BASICS,⁴ a national immunization plan was created which laid the groundwork for Moldova's first independent vaccination programme. The Government of Japan provided assistance through contributions concurrent to and in collaboration with USAID. A small amount of the World Bank funds was used by the MOH in 1995 to purchase vaccine. When USAID and the Government of Japan combined forces to meet coordinated objectives in the Japan/United States Joint Immunization Initiative in 1996, a vital supply of vaccine for children under the age of two and refrigerators for the storage of vaccine were provided to the Government of Moldova.⁵

At the time of the initial assessment in 1996, the Government of Moldova did not expect further emergency donations of EPI vaccine and had begun purchasing some vaccines and biologicals on its own from traditional suppliers in the Russian Federation and from the Pasteur Mérieux representative based in Moscow. In addition, a small amount of EPI vaccine was about to enter the system from a neighbouring country in Eastern Europe. These transactions were based on personal relationships rather than competition. Detailed

specifications did not exist, and contract wording did not provide protection against poor-quality products or failures on the part of the supplier. Epidemiologists in the Republican Sanitary and Epidemiological Station had concerns about the quality and price of the vaccine they were receiving through these procedures and asked for assistance.

A training plan had to be devised that would meet the needs of several epidemiologists and a logistics officer who had little or no procurement experience. Staffing constraints required that these individuals handle vaccine purchasing tasks in addition to their normal jobs. Development of a formal procurement unit with dedicated personnel, defined systems, and policies and procedures, while advisable, was not an option at that time. The individuals selected for procurement duties felt that learning about vaccine manufacturers and how to approach them was their number one priority. Procurement technical assistance in Moldova, therefore, focused on the development of basic skills and simple methods for procurement of safe, effective vaccines at competitive prices from the international market-place.

A guided, practice procurement was supported with periodic technical assistance from USAID/BASICS over several months, while the Ministry of Foreign Affairs of the Government of Japan supplied hard currency that was needed to pay for the vaccine. In the absence of adequate regulatory infrastructure, quality concerns were addressed by selecting a vaccine that had been approved by WHO for sale to United Nations agencies.⁶ Each step of the practice procurement was documented, leaving behind a customized, step-by-step operations manual in Russian, as well as extensive reference material.

Zimbabwe

The environment in Moldova was in distinct contrast to the situation in Zimbabwe, which, at the time of the assessment visit conducted by WHO/Vaccine Supply and Quality Unit, was enjoying one of the best economic and political situations in Africa. Vaccine procurement was being carried out on a routine basis without direct participation by UNICEF or donor agencies. The Zimbabwe EPI programme (ZEPI) benefited from having a strong, experienced manager who could coordinate and motivate key staff and influence decision-makers.

Funds for vaccine procurement came from government budgets, which originated, in part, from donations and (possibly) development loans. The Zimbabwe dollar, which is not freely convertible, was losing value, and the EPI had been forced to solicit extra funds from the government to pay its bills. Under a somewhat fragmented procurement system, the EPI manager was forecasting annual vaccine requirements and specifying programme-related attributes such as vial size. The Central Medical Stores was charged with soliciting competitive bids by advertising in local newspapers, and the Government Tender Board was responsible for selecting a winning bid. Most vaccine was purchased with Zimbabwe dollars through manufacturers' representatives who visited on a regular basis. The Medicines Control Board

(MCB) regulated vaccines through a process taking about 18 months from the time of dossier submission to the time a vaccine was licensed for use in Zimbabwe. There was no specialized committee or laboratory for biologicals within the MCB, and lot-by-lot registration at entry into the country was not done. A competent international banking system was in place, and letters of credit in foreign currencies could be issued to pay for various imported goods.

The programme of vaccine procurement technical assistance in Zimbabwe focused on overall strengthening of a system that was reliant on the combined activities of several different government units. Procurement advisors carried out a 'mapping' project that traced each step of the existing procurement process and produced a flow chart showing the exact steps and interactions of the various players along with rudimentary time estimates.⁷ With the assistance of the regional WHO office in Harare, 10 key local personnel were brought together with technical advisors for a 3-day workshop to jointly review and fine-tune the flow chart representation of the ZEPI system, compare it to the model mentioned above in conjunction with the USAID/WHO vaccine procurement reference manual, and identify key areas for improvement.

Some of the short- and mid-term needs identified by workshop participants included assistance with value-for-price determinations, improvements in data collection and analysis, improved specifications and purchase order language, further coordination of key players, and additional focus on biologicals at the MCB.

Several interesting lessons came from the Zimbabwe mapping exercise:

- The mapping process itself strengthens the system by forcing clarification of responsibility and procedure in areas that have not, in the past, been well defined.
- Weaknesses, once revealed, often have simple solutions that can be resolved internally without difficulty or cost.
- Units and individuals who have responsibility for separate parts of the supply chain may work in isolation from one another and have little understanding of the system as a whole.
- Mapping illustrates to key players and stakeholders how long it takes to complete a purchase and, consequently, how early the planning must begin.
- Bringing key players together facilitates development of collegial relationships and enables immediate action on issues of mutual concern by serving as a forum for discussion and joint problem-solving.

These case studies were presented to help the reader understand a number of important considerations associated with procurement of safe, effective vaccines, as well as to illustrate customized approaches to procurement technical assistance. This may be particularly relevant as we try to make health reforms work for immunization in widely diverse country situations (Feilden and Nielsen 1998). There are also broad organizational and systems issues that must be addressed – issues that impact directly on institutional

capacity for procurement and supply of safe, effective vaccines.

Organization and systems issues

Integration of systems

Reform efforts generally advocate adopting modern management principles, one of which is to save money by eliminating duplication. In the context of health commodities such as vaccines, contraceptives, and essential drugs, this is commonly interpreted to mean consolidation or 'integration' of the vertical/parallel supply systems that have grown up around these three different product types. Historically, separate systems for vaccines and contraceptives were established because the special requirements surrounding procurement and delivery of these products were not being met within larger drug supply systems. It seems we have come full circle; however, we must make sure the mistakes of the past are not repeated. Receipt of poor quality or unduly expensive vaccine, breaks in the cold chain, and low-priority, erratic deliveries to peripheral cold stores are just a few of the worrisome issues rooted in the fact that *vaccines are substantially and fundamentally different from drugs*.

As countries begin to embrace the idea of self-sufficiency and grapple with changes in organizational framework, and stakeholders offer assistance with building institutional capacity, an understanding of these differences is critical to establishing systems that will be effective for purchasing and delivering high-quality vaccine.

Vaccines vs. drugs

To begin with, there are physical differences to consider that affect procurement and the way delivery systems are organized. As mentioned above, vaccines are biologicals rather than chemicals: vaccine characteristics can differ from manufacturer to manufacturer, and quality is subject to lot-by-lot variation. Vaccines also have a short shelf life and require special handling in a cold chain, from point-of-manufacture to point-of-use, in order to retain potency. Not only do vaccines require a cold chain, but some vaccines also need to be protected from freezing.⁸ In addition, 'wastage' is an expected and necessary part of the system because opened vials of vaccine can have a relatively short period of safe use – sometimes as little as a few hours – before they must be discarded.⁹

Moreover, vaccine quality-assurance practices differ from those of drugs. While samples of incoming pharmaceuticals are frequently tested in national laboratories before being released for use, it is not practical to mimic this process for vaccine arriving in a non-producing country. Laboratory analysis for biologicals takes much longer than for drugs and is quite expensive. It requires special equipment, animals, and animal laboratories, as well as specially trained staff. Because the number of vaccine shipments per year is minimal, reflecting a very small product volume compared to drugs, expensive laboratory facilities and staff can stand idle for substantial periods. Instead, non-producing countries are encouraged to develop and rely upon a strong regulatory

environment (ideally, a separate biologicals committee within the national regulatory body) rather than lot-by-lot laboratory testing for routine quality assurance.

Compared with pharmaceuticals, vaccines represent a very small number of products made by a very small number of manufacturers. Vaccine production in developing countries, where it exists, is usually confined to one or two vaccines, and local pharmaceutical wholesalers often do not have the facilities or expertise to accommodate these specialized products. It is usually more expedient, safer, and less expensive for vaccine programmes to import directly from international sources.

From an economic standpoint, the currently used standard EPI vaccines are relatively inexpensive and account for a much smaller proportion of public-sector health budgets than do pharmaceuticals. A recent World Bank estimate sets the annual cost of pharmaceuticals for developing countries at US\$44 billion and the annual cost of EPI vaccines at US\$1.4 billion. Traditional EPI vaccines (i.e. DPT, OPV, measles, BCG and TT) are usually provided free of charge by government programmes, with no cost-recovery element. Essentially, they are valueless as commercial products and are insignificant in quantity; thus, they carry little incentive for pilferage, diversion or other opportunity for personal gain. [This may not be true in the case of newer vaccines such as hepatitis and possibly, *Haemophilus influenzae* type B (Hib).] Unfortunately, the personal gain element can be a substantial factor in how efficiently a product finds its way through a supply system.

Programmatic decisions about how vaccines are administered (such as mass campaign vs. routine infant immunization and the number of doses per multidose vial) have a corresponding effect on quantity, storage, and delivery requirements. In addition, the dosage and presentation of vaccine must be closely coordinated with well-designed training materials to ensure safe use in the field. Unlike drugs, vaccines are given to healthy individuals who do not seek them out because they are feeling ill. Therefore, failures in the re-supply system translate to missed opportunities to vaccinate – the vaccine must be available when the client is available. EPI vaccines are supposed to be given to 100% of the birth cohort early in life to avoid unnecessarily exposing children to a minimum of six target diseases.¹ Combined with shelf-life and storage time/temperature constraints, this adds up to a need for more frequent deliveries to peripheral units than pharmaceuticals normally require.

Strategically, vaccine is preventive rather than curative medicine. As such, it is inextricably tied to national health programmes because the State has an obligation to protect the 'public good', i.e. prevent epidemics of infectious diseases. The availability of adequate amounts of safe, effective vaccine also has obvious global epidemiological implications.

Decentralization of systems

'Decentralization' is another popular strategy of health sector reform that raises concern with regard to vaccination

programmes (Kolehmainen-Aitken and Newbrander 1997). Decentralization can begin at any level from the top down. In a totally decentralized system, it would start with decision-making, financing and purchasing. In a partially decentralized system, it might involve only storage and distribution. The decentralization of certain components of public health management systems can have serious collateral effects with regard to efficient expenditure of scarce resources, management of vaccine supply, data collection and disease surveillance. Without a centralized, hierarchical system of some kind, economies of scale are lost when purchasing vaccine; reliable information is no longer available for estimating national requirements; accurate, consistent assessments of immunization coverage and disease surveillance statistics, using standardized definitions and procedures, are compromised; the capability to exert control over vaccine quality and appropriate usage is weakened, with a consequent serious negative impact on EPI management. All of these unintended consequences of unplanned decentralization in immunization programme management have been particularly evident in many of the countries of the NIS, where budgetary shortfalls have led to *de facto* decentralization of health systems and regional or municipal entities are purchasing their own vaccines from independent suppliers.

Decentralization at the level of vaccine procurement not only implies very small order quantities, but the need for appropriate skills to be duplicated many times over – a direct antithesis to the possible efficiencies of integrating vaccine procurement systems and a challenge to stakeholders who wish to offer practical assistance.

Concluding remarks

Self-sufficiency in vaccine supply began as a synonym for self-financing at a time when donor funds were strained, but it has grown into a much broader theme of institutional development and capacity building. Obviously, there are many different kinds of institutional development and capacity building. This article has sought to isolate procurement and supply of vaccine as pivotal elements of self-sufficiency in the operation of national immunization programmes for one very good reason: these programmes are severely compromised without adequate quantities of safe, effective vaccine. It is surprising how often strategies and plans for various health sector development or reform programmes are built around the assumption of adequate supplies, but do nothing to ensure them.

Vaccines are complicated products. They require special handling, special procurement procedures, and special quality control systems. Data collection and analysis is required as a component of national and international disease surveillance as well as for forecasting and inventory control purposes. Vaccines also have quasi-political elements. Issues such as who will purchase them, which types of vaccine will be used, and who should regulate them must be addressed, and donor agencies and other stakeholders sometimes have differing views.

Technical assistance in establishing or strengthening vaccine

procurement can be made available to governments as an alternative to (or component of) vaccine donations, or can be used to help countries in their approach to implementing health care reforms. Recent collaboration between USAID and several international organizations has been aimed at providing advice that is rational, coherent, and reflects common principles and policies.

Procurement and delivery of high-quality vaccine has national and international public health and 'public good' implications far beyond the scope of most products. People immunized with vaccines of inadequate quality can become ill and die from the disease that the vaccine should have prevented. Even more lives are placed at risk if vaccination coverage declines as a result of reduced public confidence in immunization programmes. The spectre of widespread epidemic looms large in a global village where it takes only hours to move from place to place, and hundreds of millions do it every day.

As low- and middle-income countries begin moving away from donations and toward self-sufficiency with direct purchases of vaccine, specialized procurement technical assistance will be needed in order to help ensure that their populations continue to receive safe, effective products and that immunization programmes will get the most value from their expenditures. Assistance should also be provided when countries are faced with fundamental organizational and systems changes that affect immunization programmes, and whenever procurement problems are suspected.

Procurement technical assistance can be positioned as an alternative to or a component of vaccine donations. It can certainly be used to help countries in their approach to implementing health sector reforms. Recent collaboration between USAID and several international organizations has resulted in a programme that is realistic, customized to specific situations, and speaks with one voice with regard to principles and policies. It covers all aspects of vaccine procurement, including quality and regulatory issues, and is complemented by comprehensive text and reference material.

Because they influence the future shape and effectiveness of health care organizations and systems, it is critically important for decision-makers and other stakeholders to be aware of the special concerns about vaccines and to appreciate the intricacies of vaccine procurement, particularly as countries around the world begin to adopt health sector reforms. Hopefully, this article has provided guidance, both in general and in detail, about these important issues and the resources available to help developing-country governments and others make safe, effective transitions to self-sufficiency in vaccine procurement and supply.

Endnotes

¹ The Expanded Programme on Immunization (EPI) was launched by the World Health Organization in 1974. It sought universal childhood immunization against six initial target diseases (diphtheria, tetanus, whooping cough, polio, measles and tuberculosis). The basic EPI vaccines are BCG (Bacillus of Calmette and Guérin – for immunization against tuberculosis), DPT (Diphtheria-Pertussis-Tetanus and variations, and Tetanus Toxoid), measles and

OPV (Oral Polio Vaccine). EPI-Plus adds yellow fever and hepatitis B to the initial target diseases.

² Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine, Uzbekistan, plus the Baltic countries of Estonia, Latvia and Lithuania, which are included for convenience.

³ UNICEF procurement service requires an advance deposit in convertible currency equal to the estimated cost of supplies plus an administrative fee of 6–8%, estimated freight costs, and a refundable contingency deposit of 10% of the value of the transaction.

⁴ USAID/BASICS/PATH Procurement technical assistance in Moldova [Woodle reports: March 1994, April 1996, July 1996].

⁵ Trip report on the participation at the Fourth Meeting of the Interagency Immunization Coordinating Committee, April 1996, Brussels, Belgium, by Robert Steinglass.

⁶ The WHO process includes a thorough investigation of manufacturing conditions, quality assurance practice and records, and characteristics of the specific vaccine as well as its regulatory status. WHO relies to a great extent on international experts and the National Control Authority in the country of manufacture for information necessary to the approval process.

⁷ Joint assistance by USAID/BASICS/PATH and WHO in Zimbabwe [unpublished reports, March 1998, July 1998].

⁸ IPV, DPT, DT, hepatitis B, and TT vaccines are seriously damaged by being frozen.

⁹ Opened vials of measles, yellow fever and BCG vaccines must be discarded at the end of each immunization session.

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